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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,850	11/18/2005	Brian Neil Zeiler	567.1009	7984
23280 7590 11/28/2007 DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018			EXAMINER TUNG, JOYCE	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 11/28/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,850	<b>Applicant(s)</b> ZEILER, BRIAN NEIL	
	<b>Examiner</b> Joyce Tung	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/11/06, 6/20/05</u> | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Claim Objections*

1. Claims 6 and 19 are objected to because of the following informality: the phrase "represented B" might be a grammatical error. Appropriate correction is required.
2. Claim 19 depends from claim 18 which is a kit claim and is not a method claim. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3-4, 9, and 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 3 is vague and indefinite because of the phrase "modifications thereto". It is unclear what is encompassed by the phrase. Clarification is required.
- b. Claim 4 is vague and indefinite because of the phrase "said reaction product" which lacks proper antecedent basis.
- c. Claim 9 is vague and indefinite because of the phrase "said T7 DNA-dependent RNA polymerase" which lacks proper antecedent basis.
- d. Claims 11-12 are vague and indefinite because of the phrase "the number two position" which has no antecedent basis.

*Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 5-6 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Guillou-Bonnici et al. (5,744,308, issued Apr. 28, 1998).

Guillou-Bonnici et al. disclose a process for obtaining transcripts or cyclic amplification with transcripts obtained of a target sequence of a nucleic acid and/or a sequence complementing said target sequence (See column 9, lines 19-27). The process applies the template which is a ribonucleic <sup>acid</sup> ~~nature~~ (See column 10, lines 43-44, column 12, lines 17-20 and column 19, lines 51-58) or a DNA target (See column 14, lines 6-8 and column 16, lines 3-5) and T7 RNA polymerases (See column 12, lines 30-37) on a single template of double strand which is an entirely DNA or RNA (See column 16, lines 44-48). Antisense sequence of an RNA polymerase promoter designates the sequence of a promoter whose 5' end is located upstream of a transcription initiation site which is defined by this same promoter (See column 6, lines 49-53).

Guillou-Bonnici et al. do not explicitly disclose the RNA having a selected sequence. However, the RNA template used in the method of Guillou-Bonnici et al. is a target sequence (See column 9, lines 19-27). It is inherent in the teachings that target sequence is a selected sequence. Thus the teachings of Guillou-Bonnici et al. anticipate the limitations of the claims.

7. Claims 14-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Axelrod et al. (5,620,851, issued Apr. 15, 1997).

Axelrod et al. disclose the use of an oligonucleotide probe for hybridization with a target nucleic acid sequence (See column 3, lines 66-67 and column 4, lines 1-4). The invention also includes kits (See column 5, lines 62-63). The kit comprises a single-stranded nucleic acid molecule comprising a nucleic acid sequence complementary to the promoter sequence of the DNA moiety of an adduct as disclosed by Axelrod et al., an RNA dependent RNA polymerase (See column 18, claims 19-21), reagents for the synthesis of transcript (See column 13, lines 14-24), means for making at least one template nucleic acid (See column 12, lines 55-58), and Q-Beta replicase (See column 12, lines 9-12).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guillou-Bonnici et al. (5,744,308, issued Apr. 28, 1998) as applied to claims 1-2, 5-6 and 8-9 above, and further in view of Axelrod et al. (5,620,851, issued Apr. 15, 1997).

The teachings of Guillou-Bonnici et al. are set forth in section 6 above. Guillou-Bonnici et al. do not disclose that RNA dependent RNA polymerase is Q-Beta replicase.

Axelrod et al. disclose that Q-Beta replicase is used for replication of RNA transcripts (See column 11 lines 37-39).

One of ordinary skill in the art would have been motivated to apply Q-Beta replicase as taught by Axelrod et al. because Q-Beta replicase recognizes certain nucleic acid sequence sites at both the 3'- and 5'- ends of the given RNA transcript (See column 11, lines 37-46). It would have been prima facie obvious to apply Q-Beta replicase as recited in the claims.

10. Claims 10-12 and 23-25 are rejected under 35 U.S.C. 103(a) as being respectively unpatentable over Guillou-Bonnici et al. (5,744,308, issued Apr. 28, 1998) as applied to claims 1-2, 5-6 and 8-9 above, and over Axelrod et al. (5,620,851, issued Apr. 15, 1997) as applied to claims 14-22 above, further in view of Burke et al. (5,637,459, issued Jun. 10, 1997).

The teachings of Guillou-Bonnici et al. and Axelrod et al. are respectively set forth in sections 6 and 7 above. Guillou-Bonnici et al. and Axelrod et al. do not disclose the limitations listed in claims 10-12 and 23-25.

Burke et al. disclose methods for producing chimeric nucleic acid molecules (See column 2, lines 52-53). The method applies modified nucleotides at the 2' position as recited in claims 12 and 20 (See column 4, lines 9-11).

One of ordinary skill in the art would have been motivated to apply modified nucleotides at the 2' position as recited in claims 12 and 20 (See column 4, lines 9-11) for making double stranded RNA and for inclusion in a kit for making double stranded RNA because by using modified nucleotides at the 2' position as recited in claims 12 and 20 (See column 4, lines 9-11), chimeric nucleic acid molecules would not be susceptible to endonucleases that rely on 3' to 5' degradation and would yield desirable in vivo therapeutic and diagnostic agents (See column 3, lines 49-52). It would have been prima facie obvious to apply the modified nucleotides at 2' position as recited in claims 12 and 20 for making double stranded RNA. Moreover, it would have also been prima facie obvious for one of ordinary skill in the art to make a kit including modified nucleotides at the 2' position as recited in claims 12 and 20 for making double stranded RNA because of the benefit as discussed above. It was also routine practice in the art to make a kit for conveniently performing a method.

11. Claims 4, 13 and 26 are rejected under 35 U.S.C. 103(a) as being respectively unpatentable over Guillou-Bonnici et al. (5,744,308, issued Apr. 28, 1998) as applied to claims 1-2, 5-6 and 8-9 above, and over Axelrod et al. (5,620,851, issued Apr. 15, 1997) as applied to claims 14-22 above and further in view of Elbashir et al. (Gene & Development, Vol. 15, pg. 188-200, 2001).

The teachings of Guillou-Bonnici et al. and Axelrod et al. are respected set forth in sections 6 and 7 above. Guillou-Bonnici et al. and Axelrod et al. do not disclose the limitations recited in claims 4, 13 and 26.

Elbashir et al. disclose that double stranded RNA induces sequence-specific posttranscriptional gene silencing in many organisms by a process known as RNA interference

(RNAi). Short interfering RNAs (siRNAs) are generated by an RNase III-like processing reaction from long dsRNA (See pg. 188, the Abstract). Specific inhibition of target RNA expression was detected for dsRNA as short as 38bp, but dsRNAs of 29-36 bp were not effective in this process (See pg. 189, column 1, second paragraph). Since claim 3 recites that said reaction product comprising double stranded RNA inhibits the expression of a selected gene in a cell, this teaching satisfies the limitations of claim 3. Moreover, claims 13 and 26 recite that said amplification product is used for RNAi. Elbashir et al. disclose that the double stranded RNA is used for RNAi (See pg. 189, column 1, second paragraph and column 2, first paragraph).

One of ordinary skill in the art would have been motivated to apply the method of Elbashir et al. to the expression of a selected gene in a cell and for using the amplification product for RNAi because Elbashir et al. provide evidence that the direction of dsRNA processing determines whether sense or antisense target RNA can be cleaved by the siRNA-protein complex (See the Abstract). It would have been prima facie obvious to perform the limitations in claims 4, 13 and 26.

### **Summary**

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

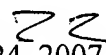
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.




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Joyce Tung   
November 24, 2007

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

11/26/07